Paper No. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RICHARD ROSENBLOOM

Appeal No. 2004-0340
Application No. 09/847,121

ON BRIEF

Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-6, 10, 12, 13, and 15. Claims 7-9, 11, and 14 are also pending but have been withdrawn from consideration. Claim 1 is representative and reads as follows:

1. A composition for the treatment of diabetic neuropathy by a method of administration selected from the group consisting of oral administration, parenteral administration and inhalation, the composition comprising a mixture of an amount of a compound that promotes synthesis of nerve growth factor selected from the group consisting of vitamin D_3, 1(S), 3(R)-dihydroxy-20(R)-(1-ethoxy-5-ethyl-5-hydroxy-2- heptyn-1-yl)-9, 10-seco-pregna-5(Z), 7(E), 10 (19)-triene, pharmaceutically acceptable salts thereof and mixtures thereof, which is effective when administered in the composition to promote synthesis of nerve growth factor, an amount of an aldose reductase inhibitor which is effective when

administered in the composition to inhibit aldose reductase and an effective amount of an antioxidant.

The examiner relies on the following reference:

Riley	5,976,568	Nov. 02, 1999

Claims 1-6, 10, 12, 13, and 15 stand rejected under 35 U.S.C. § 103 as obvious in view of Riley.

We reverse.

Background

Diabetes mellitus causes long-term tissue damage. "This damage may take many forms but the major types are damage to the eyes (retinopathy), nerves (neuropathy), kidneys (nephropathy) and cardiovascular system." Specification, page 1. "There are many approaches to reducing or preventing these forms of damage. . . . [A] number of pharmaceutical companies have been developing aldose reductase inhibitors for the purpose of reducing diabetic neuropathy." Id.

The specification discloses "compositions for the treatment of diabetic neuropathy. The compositions comprise a mixture of a compound that promotes synthesis of nerve growth factor, an aldose reductase inhibitor and an antioxidant." Page 3. "Exemplary compounds that promote synthesis of nerve growth factor are vitamin D_3 [and] vitamin D_3 derivatives." Page 4. These compounds are "used in an amount effective to promote the synthesis of nerve growth factor of about 6-14.3 IU per kg of body weight of the patient." Id.

"The second active ingredient of the compositions . . . is an aldose reductase inhibitor. Numerous suitable aldose reductase inhibitors are known to persons skilled in the art." Page 5. One specific example is quercetin. Page 6, lines 11-12. "The aldose reductase inhibitor is used in an amount that provides substantially the same level of aldose reductase inhibition as 13-21.4 mg/kg body weight of the patient per day of quercetin." Page 6, lines 24-25.

"Another active ingredient in the compositions . . . is the antioxidant." Page 6, lines 31-32. Preferred antioxidants include "ascorbyl palmitate, ascorbic acid (vitamin C), vitamin A, [and] vitamin E." Page 7, lines 11-12. "Ascorbyl palmitate may be used in amounts of 11-28.6 mg/kg body weight of the patient per day. . . . When vitamin E is employed as mixed tocopherols, an amount of about 4-11.4 IU per kg body weight of the patient, per day may be employed. . . . When vitamin A is employed, an amount of about 170-357.1 IU per kg body weight of the patient, per day, is employed." Page 7, lines 22-31.

"Dosages may be administered 1-10 times per day. . . . Thus, the composition of the invention may comprise anywhere from one tenth of the daily minimum dosage of the various active ingredients up to a maximum of the daily maximum dosage of the various active ingredients." Page 10, lines 22-28.

Discussion

The claims are directed to a composition comprising three compounds: vitamin D_3 (or a specific derivative thereof) in an amount effective to promote synthesis of nerve growth factor; an aldose reductase inhibitor in an amount effective to inhibit aldose reductase; and "an effective amount of an antioxidant."

The examiner rejected the claims as obvious in view of Riley, reasoning that Riley

> discloses an oral daily supplement composition comprising Vitamins A, D, E, C (Buffered Calcium Ascorbate, Ascorbic Acid and Ascorbyl Palmitate) and quercetin, see claim 2. Riley . . . also discloses an oral daily supplement composition comprising vitamins A, C, D3 and E, see claim 3. See also Table II, columns 25 and 28.
>
> It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an amount [e]ffective to promote nerve growth of a vitamin D3 derivative, ascorbyl palmitate and quercetin in a single . . . composition.

Examiner's Answer, page 3. The examiner also asserted that "the interconversion of dosage forms, i.e., the conversion of two-three modular formulations into a single composition is within the skill of the artisan, and is therefore obvious." Id., page 6.

Appellant argues that Riley does not suggest combining all of the active ingredients required by the instant claims into a single composition. Rather, "Riley teaches that the total daily dosage of claim 2 should be divided into several distinct modular formulations. . . . Thus, Riley does not disclose the composition containing vitamins A, D, E, C and quercetin that the Examiner relies upon in support of the rejection." Appeal Brief, page 6 (emphases in original).

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). When determining obviousness, "the prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill." In re Hedges,

783 F.2d 1038, 1041, 228 USPQ 685, 687 (Fed. Cir. 1986). "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." Id.

In this case, we agree with Appellant that Riley would not have suggested the claimed composition. Riley teaches administration of dietary supplements in the form of a system of "modular" supplements. The modular compositions disclosed by Riley contain different combinations of vitamins, minerals, etc. For example, "Module 1, the basic formula, . . . consists of vitamins and minerals essential for the prevention of vitamin and mineral deficiency diseases and for the promotion of general good health." Column 4, lines 51-55. Module 1 contains, among other things, vitamins A, C, D3, and E. See Table 2 in columns 25-26. Module 1 does not contain quercetin. See id.

Module 3, on the other hand, is for "assisting in the reduction of risk factors of chronic disease such as coronary heart disease and cancer. It contains not only the basic daily nutrient needs, but specific doses of vitamin[s], minerals and other compounds, such as antioxidants and folic acid, which have been found to reduce some of the nutritional determinants of these diseases." Column 5, lines 3-9. Module 3 contains quercetin and vitamins A, C, and E. See Table 2. Module 3 does not contain vitamin D3. See id.

Riley teaches that providing different supplements in different compositions provides advantages over conventional vitamin supplements. The

modular formulations "provide the right amount of the right micronutrients at the right time to avoid and overcome the problems commonly seen with vitamin supplementation today." Column 5, lines 22-25.

Thus, Riley describes the disclosed modular formulations as providing advantages over compositions comprising all of the disclosed micronutrients in a single composition. Modifying the reference's teaching as suggested by the examiner—by combining the components of the different modules into a single composition—would destroy the very advantages touted by Riley. Thus, we do not agree with the examiner that Riley would have rendered obvious the composition of the instant claims.

The examiner argues that Riley discloses that "Modules 1-3 . . . may be administered together or independent of one another." Column 6, lines 40-42. Thus, "[i]f one were to consider each module as a dosage form such as a tablet, following the teaching of Riley one would take the three tablets (Modules 1-3) concomitantly." Examiner's Answer, page 4. The examiner argues that Appellant's argument—that three tablets do not suggest a single composition—amounts to an argument that "the difference between the instant claims and Riley's teaching is that Riley teaches a modular formulation comprising Vitamins A, C, D, E and quercetin in more than one tablet while appellant teaches Vitamins A, C, D, E and quercetin in a single tablet." Examiner's Answer, page 5.

We agree with the examiner that this difference is what distinguishes the claimed composition from those disclosed in the prior art. We also agree with the

examiner's statement that "[t]he reference should be taken as a whole and all of its teachings must be considered." Examiner's Answer, page 6.

Where we disagree with the examiner is in the conclusion to be drawn from applying the correct legal standard to the facts of this case. The examiner seems to believe that combining the components of two separate dietary supplement compositions into a single composition is such a trivial difference that the claimed composition would be prima facie obvious even in the absence of a suggestion to modify the prior art compositions. We disagree.

"[I]dentification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant." In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000). "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." Id. at 1370, 55 USPQ2d at 1316. No such suggestion is apparent here.

Summary

The examiner has not adequately explained why Riley would have suggested, to a person skilled in the art, a single composition combining the components of the prior art's Modules 1 and 3. In the absence of such a suggestion, the reference does not support a prima facie case of obviousness. The rejection under 35 U.S.C. § 103 is reversed.

REVERSED

Demetra J. Mills Administrative Patent Judge	)
Eric Grimes Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Lora M. Green Administrative Patent Judge	)

EG/dym

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